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Document Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD. 20852

Re: Docket No. 97N-484S

To Whom It May Concern:

I am writing to express my grave concern about the FDA becoming involved in the management of allograft tissue. Orthopaedic surgeons in the United States have been successfully and safely using allograft tissue for many years. The safety controls from the institutions that provide these have in my twenty years of experience as an **orthopaedic** surgeon been much more than satisfactory. Having lost a child and being involved in the organ donation process, I am aware of the tremendous lengths to which the organ procurement companies go to insure that donors are safe and acceptable donors of the tissues that they get from these donors. Further, these companies cannot afford the legal consequences of a recipient receiving contaminated tissue. The legal consequences would be devastating to the industry. I, therefore, believe there are so many constraints on the bone banking and tissue banking industry that FDA supervision would make the process more cumbersome and unnecessarily limit the supply of allograft tissue which is so desperately needed.

Sincerely,

G. Lee Cross, III, M.D.

kms

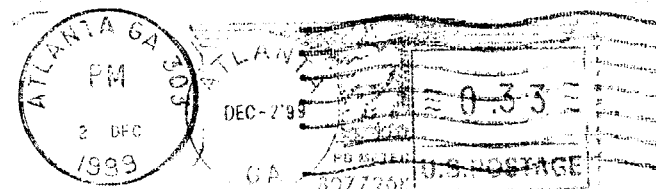
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BONE AND JOINT
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ADDRESS CORRECTION REQUESTED



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